PATENT
Customer No.: 22,852
Attorney Docket No.: 08203.0030-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	
Frank BONADIO et al.	)	Group Art Unit: 3772
	)	
Application No.: 10/600,812	)	Examiner: Bianco, Patricia
	)	
Filed: June 20, 2003	)	
	)	
For: APPARATUS FOR USE IN SURGERY AND A VALVE	)	Confirmation No.: 7588

Attention: Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPEAL BRIEF UNDER BOARD RULE § 41.37

In support of the Notice of Appeal filed September 3, 2009, and further to Board Rule 41.37, Appellant presents this brief and submits herewith the fee payment of $540.00 required under 37 C.F.R. § 41.20(b)(2). Appellant also submits herewith a Petition for Extension of Time of one month and fee payment paid electronically at the time of filing, extending the due date for filing the brief to December 3, 2009.

This Appeal is in response to the final rejection of claims 26-40, 42-55, 73-85, and 87-110 in the Final Office Action ("Office Action") mailed March 3, 2009.

If any additional fees are required or if the submitted payment is insufficient, Appellant requests that the required fees be charged to Deposit Account 06-0916.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is Atropos Limited, the assignee of the entire right, title, and interest in the application.

II. RELATED APPEALS AND INTERFERENCES

This application is a continuation of U.S. Application No. 08/641,811, filed May 2, 1996, now abandoned. On August 15, 2001, the Board issued a judgment in Patent Interference No. 104,195. Appellant has attached a copy of the judgment to this Appeal Brief (see Exhibit F).

There are currently no other appeals or interferences, of which Appellant, Appellant's legal representative, or Assignee are aware, that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-72, 86, 101-105, and 108-110 have been previously cancelled without prejudice or disclaimer. Claims 73-85, 87-100, 106, and 107 are pending in this application, with claims 106 and 107 being independent. Claims 73-85, 87-100, 106, and 107 have been finally rejected in the Office Action, and the rejections of those claims are at issue in this Appeal. A copy of the pending claims is provided in the attached Claims Appendix to this Appeal Brief.

IV. STATUS OF AMENDMENTS

An Amendment was filed on August 21, 2009, subsequent to the rejection of the claims in the Office Action. The Amendment has been considered by the Examiner, and will be entered for purposes of appeal, as indicated in the Advisory Action mailed on October 19, 2009. Thus, the issues discussed in this Appeal Brief are consistent with the entry of the August 21, 2009 Amendment. The Amendment cancelled claims 26-40, 42-55, 101-105, and 108-110, leaving claims 73-85, 87-100, 106, and 107 pending in this application. By the cancellation of claims 26-40, 42-55, 101-105, and 108-110 and presentation of a new Fig. 9, the Amendment remedies the objection to the drawings under 37 C.F.R. § 1.83(b), and objections to the specification under 37 C.F.R. § 1.75(d)(1) and M.P.E.P. § 608.01(o), in accordance with pages 8 and 9 of the Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following is a summary and explanation of the subject matter of the pending independent claims.

A. Independent Claim 106

Referring to Fig. 9 of the instant application (reproduced below), the subject matter set forth in independent claim 106 relates to a surgical device (60)[1] providing sealed access through an incision (in body tissue 30) in a patient. See Specification, page 9, lines 27-29; and Fig. 9.

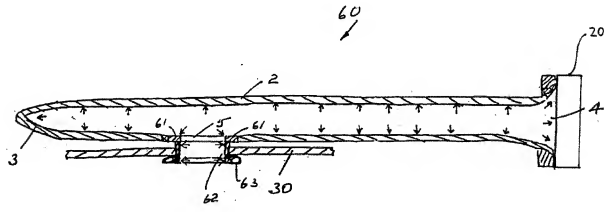


Fig. 9

Device (60) comprises a distal ring (63) insertable through the incision to engage internal body tissue. See id. at page 9, line 33; page 10, line 1; and Fig. 9. Device (60) also comprises a tubular diaphragm (62) having a distal end, a proximal end, and an incision engaging portion. See id. at page 9, lines 30-33; page 10, lines 1 and 2; and

[1] The references to the specification and drawings in this Appeal Brief are merely intended to facilitate explaining how the originally-filed application provides exemplary embodiments and exemplary disclosure relating to the claimed subject matter. Those references should not be construed as limiting the claims.

Fig. 9. The distal end of tubular diaphragm (62) is coupled to distal ring (63). See id. at page 9, lines 32 and 33; and Fig. 9. The incision engaging portion is configured to engage the incision. See id. at Fig. 9. The proximal end of tubular diaphragm (62) is located proximal distal ring (63) and outside the incision. See id. at page 9, lines 30 and 31; and Fig. 9. Device (60) further comprises an entry seal assembly (20) located proximal tubular diaphragm (62). See id. at page 7, lines 20-28; and Figs. 3-7 and 9. Entry seal assembly (20) is configured to maintain a controlled pressurized environment inside surgical device (60) such that the engagement of the incision engaging portion of diaphragm (62) with the incision and engagement of distal ring (63) to the internal body tissue increases with an increase in pressure within the controlled pressurized environment. See id. at page 8, lines 28-33; page 10, lines 1-4; and Fig. 9.

B. Independent Claim 107

The subject matter set forth in independent claim 107 relates to a surgical device (60) providing sealed access through an incision (in body tissue (30)) in a patient. See Specification, page 9, lines 27-29; and Fig. 9. Device (60) comprises a distal ring (63) insertable through the incision to engage internal body tissue. See id. at page 9, line 33; page 10, line 1; and Fig. 9. Device (60) also comprises a tubular diaphragm (62) having a distal end, a proximal end, an internal portion, and an incision engaging portion opposite the internal portion. See id. at page 9, lines 30-33; page 10, lines 1 and 2; and Fig. 9. The distal end of tubular diaphragm (62) is coupled to distal ring (63) and the proximal end of tubular diaphragm (62) is located proximal distal ring (63) and outside the incision. See id. at page 9, lines 30 and 31; and Fig. 9.

Device (60) further comprises an entry seal assembly (20) located proximal tubular diaphragm (62) and configured to maintain a controlled pressurized environment inside surgical device (60). See id. at page 7, lines 20-28; page 8, lines 28-33; page 10, lines 1-4; and Figs. 3-7 and 9. The engagement of distal ring (63) to the internal body tissue providing a seal such that the incision engaging portion of tubular diaphragm (62) is not subject to the controlled pressurized environment, while the internal portion of tubular diaphragm (62) is subject to the controlled pressurized environment. See id. at page 8, lines 28-33; page 10, lines 1-4; and Fig. 9.

VI. GROUNDS OF REJECTION

Claims 73-85, 87-100, 106, and 107 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. See Office Action at page 10.

Claims 73-85, 87-100, 106, and 107 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,640,977 to Leahy et al. ("Leahy"). See id. at page 12.

Claims 73-85, 87-100, 106, and 107 stand rejected under 35 U.S.C. § 102(g), over the sole lost count of Patent Interference No. 104,195. See id. at page 16.

VII. ARGUMENT

A. Summary of Argument

The rejection of claims 73-85, 87-100, 106, and 107 under 35 U.S.C. § 112, first paragraph is improper because a person skilled in the art would clearly understand that Appellant was in possession of the subject matter recited in the claims at the time the application was filed. For example, the device illustrated in Fig. 9 and discussed in the paragraph bridging pages 9 and 10 of the application support the claim recitation "an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a controlled pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment," of claim 106. For similar reasons, the subject language of claim 107 is supported. Since the rejection is improper, it should be reversed.

The rejection of claims 73-85, 87-100, 106, and 107 under 35 U.S.C. § 102(e) should be reversed. First, Leahy fails to teach, or even suggest, each and every feature recited in the claims. For example, Leahy fails to disclose or suggest "an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a controlled pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment," of claim 106, and "an entry seal assembly located proximal the tubular diaphragm and configured to maintain a

controlled pressurized environment inside the surgical device, the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment," of claim 107. Second, with respect to the Examiner's reliance on the claims of Leahy to anticipate the claims of this application, Applicant submits that whether or not the claims of Leahy "read upon" or dominate Fig. 9 of the present application, or are in some aspects broader than the pending claims in Appellant's application, is irrelevant to a rejection under 35 U.S.C. § 102(e). Third, the Examiner's reliance upon statements made by Appellant in Patent Interference No. 104,195, concerning whether the Leahy device covers the embodiment of Fig. 9 of Appellant's application, are also irrelevant to the anticipation analysis. For at least the above reasons, the rejection is improper and should be reversed.

The rejection of claims 73-85, 87-100, 106, and 107 under 35 U.S.C. § 102(g) should be reversed because interference estoppel is not applicable against the claims. First, for similar reasons to the traversal of the 35 U.S.C. § 102(e) rejection, the claims of this application are patentably distinct over the sole lost count of Patent Interference No. 104,195, and thus, the first type of interference estoppel does not apply. See M.P.E.P. § 2308.03. Second, Appellant is not seeking from the Examiner relief that could have been sought in the interference, and thus, the second type of interference estoppel does not apply. See id. For at least the above reasons, the estoppel-based rejection of the claims is improper and should be reversed.

B. The Rejection Under 35 U.S.C. § 112, First Paragraph Should be Reversed

In the Office Action, the Examiner rejected claims 73-85, 87-100, 106, and 107 under 35 U.S.C. § 112, first paragraph, because subject matter included in the claims is allegedly not supported by the originally-filed application. See Office Action at page 10. In particular, the Examiner alleges that, with respect to independent claim 106, "the limitation of an entry seal assembly located ***such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases in pressure within the controlled pressurized environment*** is not supported" (emphasis in original). Id. The Examiner also alleges that, with respect to independent claim 107, "the limitation of the engagement of the distal ring to the internal body tissue providing ***a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment*** is not supported" (emphasis in original). Id. at page 11.

Appellant respectfully disagrees with the Examiner's allegations. Appellant submits that the recitation, "the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment," and the recitation, "the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment," in independent

claims 106 and 107, respectively, are supported by the originally-filed application in accordance with the requirements of 35 U.S.C. § 112, first paragraph.

According to The Manual of Patent Examining Procedure (8th ed. rev. 7 Jul. 2008) ("M.P.E.P."), "[t]o comply with the written description requirement of 35 U.S.C. 112, para. 1 . . . each claim limitation must be expressly, implicitly, or inherently supported in the originally-filed disclosure." M.P.E.P. § 2163(II)(A)(3)(b). Appellant respectfully submits that independent claims 106 and 107 meet the support requirement, and thus, are in compliance with 35 U.S.C. § 112, first paragraph and the M.P.E.P.

i. The rejection of claims 73-85 and 106 should be reversed because the claims are adequately supported by the originally-filed disclosure

The rejection of claims 73-85 and 106 under 35 U.S.C. § 112, first paragraph, is improper and should be reversed because the recitation of "the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment" in independent claim 106 would have been considered by a person skilled in the art to be at least implicitly or inherently, if not expressly, supported by the originally-filed application. For example, the paragraph bridging pages 9 and 10 of the originally-filed disclosure describes a sealing diaphragm in Fig. 9 that includes

> a first ring 61 . . . a flexible diaphragm 62 extending from the ring 61 and terminating in an inner ring 63 which is inserted through the incision to engage with the body tissue 30 as illustrated. The sealing diaphragm seals the exit 5 of the sleeve 2 to the incision in the patient's body to create a controlled pressurized environment in the sleeve 2.

(emphasis added). Fig. 9 of the application has been reproduced below.[2]

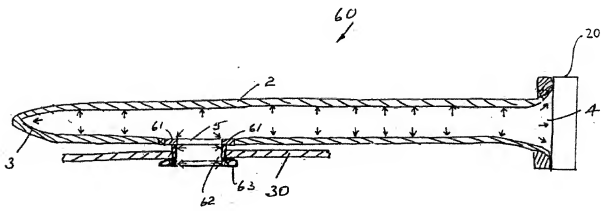


Fig. 9

As shown in reproduced Fig. 9, flexible diaphragm 62 extends through the incision. When gas is pumped into the body cavity, the pumped gas flows through flexible diaphragm 62 and fills sleeve 2, creating the controlled pressurized environment. With entry 4 of sleeve 2 being sealed by entry sealing means 20, and exit 5 being sealed to the incision, the gas pressure in flexible diaphragm 62 and sleeve 2 will increase, creating the controlled pressurized environment therein, represented by the plurality of arrows in Fig. 9. See Specification, page 8, lines 20-33. It is at least inherent or implicit that the pumping of the gas into the body cavity, and the increase in gas pressure produced by it, will urge sleeve 2 and flexible diaphragm 62 relative to body tissue 30 in an upward direction in reproduced Fig. 9 above.

[2] Appellant notes that this Fig. 9 has been amended. This amended Fig. 9 has been approved by the Examiner and is supported by the originally-filed disclosure.

Inner ring 63, however, will engage with body tissue 30, keeping flexible diaphragm 62 from sliding out of the incision. Inner ring 63 is shown performing this function in reproduced Fig. 9 above. As more gas is pumped into the body cavity, and gas pressure therein increases, sleeve 2 and flexible diaphragm 62 will be increasingly urged relative to body tissue 30 in the upward direction. Under such conditions, it is at least implicit or inherent that the contact force between inner ring 63 and body tissue 30 will also increase as ring 63 holds flexible diaphragm 62 and sleeve 2 in place.

As inner ring 63 keeps sleeve 2 and flexible diaphragm 62 in place in the face of increasing gas pressure in the body cavity, and the resultant urging the increase produces, it is at least implicit or inherent that the increased gas pressure will tend to expand the interior volume of sleeve 2 and flexible diaphragm 62. Since flexible diaphragm 62 is held so that it is at least partially in contact with body tissue 30 that forms the incision, its expansion will increase its engagement with the incision.

Appellant respectfully submits that for at least the above reasons, a person skilled in the art would have considered the recited features in independent claim 106 ("an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a controlled pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment") to be supported, at least implicitly or inherently, if not expressly, by the originally-filed application. Therefore, the rejection of claims 73-85 and 106 under 35 U.S.C. § 112, first paragraph, is improper and should be reversed.

ii. The rejection of claims 87-100 and 107 should be reversed because the claims are adequately supported by the originally-filed disclosure

The rejection of claims 87-100 and 107 under 35 U.S.C. § 112, first paragraph, is improper and should be reversed because the recitation of "the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment" in independent claim 107 would have been considered by a person skilled in the art to be at least implicitly or inherently, if not expressly, supported by the originally-filed disclosure.

For example, the paragraph bridging pages 9 and 10 of the originally-filed specification describes a sealing diaphragm that includes

> a first ring 61 . . . a flexible diaphragm 62 extending from the ring 61 and terminating in an inner ring 63 which is inserted through the incision to engage with the body tissue 30 as illustrated. The sealing diaphragm seals the exit 5 of the sleeve 2 to the incision in the patient's body to create a controlled pressurized environment in the sleeve 2.

(emphasis added). In order to seal exit 5 to the incision, and create the controlled pressurized environment in sleeve 2, it is at least implicit or inherent that a flow path exists that extends from the body cavity, through exit 5, and into the interior of sleeve 2, where the controlled pressurized environment is created. Thus, at least the following surfaces must form a leakproof boundary to create the flow path: a portion of the surface of inner ring 63 adjacent the contacting surface of inner ring 63 with body tissue 30, the interior surface of tubular diaphragm 62, and the interior surface of sleeve 2. Only those surfaces are subjected to the controlled pressurized environment.

Exposing other surfaces, such as the incision in body tissue 30, the exterior (i.e., incision engaging) surface of tubular diaphragm 62, or the exterior surface of sleeve 2, to the controlled pressurized environment, would require providing a leakage path in the leakproof boundary, through which gas pumped into the body cavity can travel to those surfaces. Such a leakage path, however, would prevent the controlled pressurized environment in sleeve 2 from forming. Accordingly, only those surfaces forming the leakproof boundary can be subjected to the controlled pressurized environment if the controlled pressurized environment is to be achieved. Moreover, subjecting the aforementioned exterior surfaces to the controlled pressurized environment would require unsealing exit 5 from the incision, directly contradicting the express requirements set forth in the above-quoted passage from pages 9 and 10 of Applicant's specification.

Appellant respectfully submits that for at least the above reasons, a person skilled in the art would have considered the recited features in independent claim 107 ("an entry seal assembly located proximal the tubular diaphragm and configured to maintain a controlled pressurized environment inside the surgical device, the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment") to be supported, at least implicitly or inherently, if not expressly, by the originally-filed application. Therefore, the rejection of claims 87-100 and 107 under 35 U.S.C. § 112, first paragraph is improper and should be reversed.

C. The Rejection Under 35 U.S.C. § 102(e) Should be Reversed

In the Office Action, the Examiner rejected claims 73-85, 87-100, 106, and 107 under 35 U.S.C. § 102(e) as allegedly being anticipated by Leahy. See Office Action at page 12. In particular, the Examiner alleges that "Leahy anticipates the claimed invention because of admissions made by Applicant during an interference proceeding, during an Examiner's Interview on March 23, 2005, and given the fact that Leahy was declared the winning party of the interference." Id.

Appellant respectfully submits that the rejection of claims 73-85, 87-100, 106, and 107 should be reversed because Leahy does not anticipate the claims, and the Examiner's allegations do not form a proper basis for asserting anticipation.

i. The Leahy reference

Leahy discloses a surgical apparatus 10 for permitting hand-assisted laparoscopic surgery. Referring to FIGS. 3 and 4 of Leahy (reproduced below), the apparatus 10 includes an outer sleeve 18 having an axial entry opening 23a and a lateral exit opening 24, exit opening 24 being located adjacent an incision in a patient. A first sealing means is provided for sealing the exit opening 24, and a second sealing means is provided for sealing the entry opening 23a, creating a sealed chamber C in sleeve 18 that prevents gas from escaping from an insufflated abdominal cavity A. See Leahy, column 3, lines 29-33.

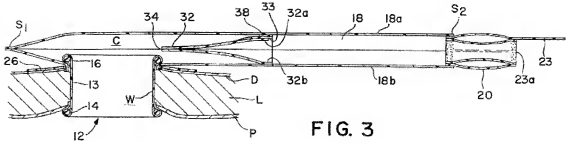


FIG. 3

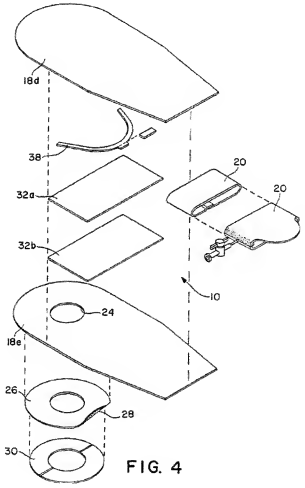


FIG. 4

The first sealing means includes an adhesive 28 on a lower exposed flange 26 of the apparatus, the adhesive being adhered directly to the patient's body or to the body by way of a drape D that is adhered to the body. See id., column 3, lines 60-67; column 5,

lines 14, 15, and 31-34; and column 7, lines 36-43. The second sealing means may include, for example, an inflatable cuff 20 located at the entry opening 23a. See id. at column 3, lines 49-54. In addition, Leahy discloses a wound protector 12 separate from the surgical apparatus 10 comprising a thin flexible tube 13 for engaging a wound W in an abdominal wall L of the patient, and flexible O-rings 14 and 16 located at opposite ends of tube 13. See id. at column 2, lines 9 and 10; and column 4, lines 1-10.

ii. The rejection of claims 73-85 and 106 should be reversed because Leahy fails to anticipate the claims

Appellant respectfully submits that the rejection of claims 73-85 and 106 should be reversed because Leahy does not anticipate the claims, and the Examiner's allegations do not form a proper basis for asserting anticipation.

a) Leahy fails to anticipate claims 73-85 and 106 because Leahy fails to disclose all of the features recited in the claims

M.P.E.P. § 2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Appellant submits that Leahy fails to disclose all of the features recited in claims 73-85 and 106, and thus Leahy does not anticipate the claims. For example, independent claim 106 recites, *inter alia*,

> an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment.

Leahy does not teach that increasing the pressure in chamber C will increase engagement of distal ring 14 and tube 13 with abdominal wall L and wound W. This is

due to the coupling of surgical apparatus 10 of Leahy to the top of abdominal wall L using flange 26 and adhesive 28. As long as flange 26 is adhered to the top of abdominal wall L, increasing pressure in chamber C will not urge tube 13 and ring 14 relative to wound W and abdominal wall L to increase their engagement with wound W and abdominal wall L. Thus, adhesive couplings, like those in Leahy, fail to utilize the insufflation pressure to assist in coupling the device to the patient. Rather, such adhesive couplings work against the insufflation pressure by tending to separate or detach at increased pressures. Therefore Leahy fails to disclose all of the features recited in independent claim 106, and cannot anticipate the claim. Moreover, nowhere does the Examiner explain where the recited features are taught in Leahy. For at least this reason, the rejection is improper. Appellant therefore respectfully requests reversal of the rejection.

b) Leahy fails to anticipate claims 73-85 and 106 because the Examiner applied an improper test for anticipation

On page 14 of the Office Action, the Examiner asserts the following basis for the rejection:

> the scope of the patented claims of Leahy are so broad they also cover a surgical device and method of providing sealed access through an incision **without the use of an adhesive** . . . . Therefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate the [claims] of the present application.

(emphasis in original). Page 14 also asserts that

> [f]urthermore, during the interference, applicant admitted in Appendix A of the Amendment filed on January 5, 1997 that claim 28 of the Leahy patent reads upon Fig. 9 . . . . In order to invoke the interference, on page 6 of Appendix A, Applicant compared patented claim 28 to Fig. 9 of the present application. Applicant's comparison and analysis of patented claim 28

> does not indicate that the adhesive or flange is required when interpreting the scope of this claim. Thus, Applicant acknowledges that the Leahy's device can be used without an adhesive and covers the embodiment of Figure 9 of the present application.

Appellant respectfully traverses the above assertions, and submits that they cannot support an anticipation rejection. Consistent with the scope of the detailed description of Leahy, the claims of Leahy do not disclose or suggest the claimed "engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment," of independent claim 106. Accordingly, the claims of Leahy cannot anticipate claim 106.

In an attempt to remedy this deficiency of the claims of Leahy, the Examiner asserts that the claims of Leahy "are so broad they also cover a surgical device and method of providing sealed access through an incision **without the use of an adhesive**" (emphasis in original) and "[t]herefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate the [claims] of the present application." Office Action, page 14. The breadth of the claims of Leahy, however, are not relevant to the issue of whether they anticipate the claims of the present application.

When asserting that the claims of a reference anticipate the claims of an application, the appropriate test for anticipation is whether the claims of the reference (Leahy) expressly or inherently include every element of the rejected claims of this application. This type of analysis frequently arises in the context of double patenting rejections where claims of one patent application (or issued patent) are used to reject

claims of another patent application. M.P.E.P. § 804 supports the distinction between breadth (or dominance) of claims and anticipation by stating:

> Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.

(emphasis added).

Accordingly, whether or not the claims of Leahy "read upon" or dominate Fig. 9 of the present application, or are in some aspects broader than the claims of the present application, is irrelevant to the anticipation analysis. Moreover, the claims of Leahy cannot cover what is not disclosed in Leahy, and thus, the claims of Leahy cannot anticipate the claims.

Similarly, the Examiner's comments alleging that statements in the relevant interference proceeding amount to an acknowledgement by the Appellant that the Leahy device "covers the embodiment of Figure 9 of the present application" are also irrelevant to the anticipation analysis. Office Action, page 14. Along these same lines, Appellant disagrees with the comments in the Office Action alleging that certain statements in the relevant interference proceeding concerning the scope of the claims of Leahy are an acknowledgement that "the claims of Leahy's device can be used without an adhesive." Id. at page 14. Even assuming the statements made during the relevant interference proceeding were to amount to an admission that the scope of certain claims of Leahy were broad enough to cover the device depicted in Fig. 9 of the

present application, such statements would in no way imply that the claims disclose the features claimed in independent claim 106 of this application.

For these additional reasons, Appellant submits that independent claim 106 is not anticipated by either the claims or detailed description of the Leahy patent. Accordingly, Appellant requests reversal of the claim rejection. Additionally, the rejection of claims 73-85 that depend from claim 106 should also be reversed for at least the reasons provided above.

c) Leahy fails to anticipate claims 73-85 and 106 because Leahy is not prior art under 35 U.S.C. § 102(e)

Moreover, the rejection is improper because Leahy is not prior art under 35 U.S.C. § 102(e). Appellant's claims are entitled to the priority date of at least Irish Patent Application No. 930649, filed September 6, 1993 ("the '649 application), under 35 U.S.C. § 119(d). The '649 application lists Frank Bonadio and Patrick Leahy as inventors. Patrick Leahy, however, is not listed as an inventor in the present application. Rather, the present application lists Frank Bonadio and Alan Reid as inventors. In situations such as this were there is an inconsistency in inventorship between a foreign priority application and a nonprovisional application claiming benefit to the priority application, the PTO suggests that the priority date should be refused until the inconsistency is resolved. See M.P.E.P. § 201.15.

The patent laws of Ireland do not require that the actual inventors be listed initially on an Irish patent application, nor does the inventorship identified initially on an Irish patent application affect the validity of an Irish patent. (See Declaration of Denis McCarthy, Exhibit A). Under Irish patent law, there is a period of 16 months from the

filing date of an Irish patent application to provide details of inventorship and derivation of rights. Since the '649 application was only used for priority purposes and was thus abandoned after 12 months, there was no need to conduct an inventorship investigation with respect to the '695 application. Accordingly, an inventorship investigation was not necessary prior to filing the '649 application and any error in the listing of Patrick Leahy as inventor on the '649 application was not legally significant.

Inventorship is resolved by looking to the claims and determining the inventorship for each claims. See 35 U.S.C. § 116. The present application includes independent claim 106 that recites, *inter alia*, "an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment." On page 14 of the Office Action, the Examiner equated claim 106 to one or more of previously pending claims 25-55 and 72-104 from Appellant's Reply to Office Action filed January 5, 2006. Thus, the Declarations of Frank Bonadio and Alan Reid (see Exhibits B and C), submitted with the Reply to Office Action filed January 5, 2006, are applicable to claim 106. As explained in the Declarations, Frank Bonadio and Alan Reid conceived of this subject matter and Patrick Leahy did not.

Appellant submits herewith as Exhibit D a final order from an Irish High Court prohibiting Patrick Leahy from representing that he is an inventor of "Dexterity the Amendments and Twist Valve." Dexterity and the Amendments correspond to the subject matter of the '649 application (Exhibit E). This order from the Irish court

supports the position that Patrick Leahy is properly omitted as an inventor from the present application.

In view of the above, Appellant submits that the inventorship inconsistency between the '649 application and the present application has been satisfactorily explained. Thus, Appellant is entitled to the benefit of the priority date of at least the '649 application. Accordingly, Leahy is not prior art under 35 U.S.C. § 102(e): Leahy was filed on September 2, 1994, while the subject matter of the present application should be accorded the benefit of the September 6, 1993, priority filing date of the '649 application. Therefore the rejection is improper and should be reversed.

Further, contrary to page 5 of the Office Action, the Board of Patent Appeals and Interferences ("BPAI") has not held that as a matter of law that Applicant is not entitled to the priority date of the '649 application. First, to the extent that the withholding of the priority date is based on estoppel, Appellant's showing of lack of anticipation over Leahy above renders that basis moot. See Office Action, pages 5 and 6; and the Interview Summary mailed April 29, 2008. Further, case law, and in particular, In re Deckler, 977 F.2d 1449 (Fed. Cir. 1992), does not support the withholding of the priority date of the '649 application from Appellant. The sole issue in Deckler was whether the losing party in an interference proceeding is entitled to a patent covering claims the party admits are patentably indistinguishable from the claim involved in the interference. See id. at 1450. Appellant, however, is seeking claims that are patentably distinguishable from the claim involved in the interference. Thus, Deckler is inapplicable to the present case. Moreover, Deckler deals with preclusion as to claims, and is silent as to preclusion as to priority under 35 U.S.C. § 119(d).

Furthermore, the BPAI's denial of Appellant's right to the priority date under 35 U.S.C. § 119(d) came in the form of a decision on a preliminary motion. A decision on a preliminary motion in an interference proceeding is not a final judgment for res judicata or estoppel purposes. See Curtis Mfg. Co., Inc. v. Plasti-Clip Corp., 933 F. Supp. 94, 103 (D.N.H. 1995) ("the court finds and rules that the decision reached by the APJ on the parties' preliminary motions in the interference proceeding is not a 'final judgment' as that term is construed for res judicata or collateral estoppel purposes"). For this additional reason, Appellant is not barred from seeking benefit of the priority date of the '649 application, but rather, is entitled to the priority date. Therefore the rejection of the claims under 35 U.S.C. § 102(e) is improper and should be reversed.

iii. The rejection of claims 87-100 and 107 should be reversed because Leahy fails to anticipate the claims

Appellant respectfully submits that the rejection of claims 87-100 and 107 should be reversed because Leahy does not anticipate the claims, and the Examiner's allegations do not form a proper basis for asserting anticipation.

a) Leahy fails to anticipate claims 87-100 and 107 because Leahy fails to disclose all of the features recited in the claims

As noted above, M.P.E.P. § 2131 states that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Appellant submits that Leahy fails to disclose all of the features recited in claims 87-100 and 107, and thus, Leahy does not anticipate the claims. For example, independent claim 107 recites, *inter alia*,

> the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment.

Leahy discloses that flange 26 and adhesive 28 form the first sealing means. See Leahy, column 3, lines 60-67. As long as flange 26 is adhered to the top of abdominal wall L, pressure in chamber C will not urge tube 13 and ring 14 relative to wound W and abdominal wall L. This suggests that flange 26 of Leahy acts as a boundary structure having a first side (below flange 26 in FIG. 3) subject to the same pressure as the pressurized gas in cavity A, and a second side (above flange 26 and outside of sleeve 18 in FIG. 3) subject to atmospheric pressure. Since both the wound engaging portion of tube 13 and the internal portion of tube 13 are on the first side of the boundary (below flange 26 in FIG. 3), they are both subject to the pressure associated with the pressurized gas in cavity A. Therefore Leahy fails to disclose all of the features recited in independent claim 107, and cannot anticipate the claim. Moreover, nowhere does the Examiner explain where this feature is taught in Leahy. For at least these reasons, the rejection is improper and Appellant therefore respectfully requests reversal of the rejection.

b) Leahy fails to anticipate claims 87-100 and 107 because the Examiner applied an improper test for anticipation

Appellant respectfully requests reversal of the rejection for additional reasons. On page 14 of the Office Action, the Examiner asserts the following basis for the rejection:

> the scope of the patented claims of Leahy are so broad they also cover a surgical device and method of providing sealed access through an incision **without the use of an adhesive** . . . . Therefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate the [claims] of the present application.

(emphasis in original). Page 14 also asserts that

> [f]urthermore, during the interference, applicant admitted in Appendix A of the Amendment filed on January 5, 1997 that claim 28 of the Leahy patent reads upon Fig. 9 . . . . In order to invoke the interference, on page 6 of Appendix A, Applicant compared patented claim 28 to Fig. 9 of the present application. Applicant's comparison and analysis of patented claim 28 does not indicate that the adhesive or flange is required when interpreting the scope of this claim. Thus, Applicant acknowledges that the Leahy's device can be used without an adhesive and covers the embodiment of Figure 9 of the present application.

Appellant respectfully traverses the above assertions, and submits that they cannot support an anticipation rejection. Consistent with the scope of the detailed description of Leahy, the claims of Leahy do not disclose or suggest the claimed "engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment," of independent claim 107. Accordingly, the claims of Leahy cannot anticipate claim 107.

In an attempt to remedy this deficiency of the claims of the reference (Leahy), the Examiner asserts that the claims of Leahy "are so broad they also cover a surgical device and method of providing sealed access through an incision **without the use of an adhesive**" (emphasis in original) and "[t]herefore, the patented claims of Leahy read upon Figure 9 of the present application and anticipate the [claims] of the present application." Office Action, page 14. The breadth of the claims of Leahy are not,

however, relevant to the issue of whether they anticipate the claims of the present application.

As noted above, in the context of rejection application claims in view of claims of a reference, the appropriate test for anticipation is whether the claims of Leahy expressly or inherently include every element of the rejected claims of this application. This type of analysis frequently arises in the context of double patenting rejections where claims of one patent application (or issued patent) are used to reject claims of another patent application. M.P.E.P. § 804 supports the distinction between breadth (or dominance) of claims and anticipation by stating:

> Domination and double patenting should not be confused. They are two separate issues. One patent or application "dominates" a second patent or application when the first patent or application has a broad or generic claim which fully encompasses or reads on an invention defined in a narrower or more specific claim in another patent or application. Domination by itself, i.e., in the absence of statutory or nonstatutory double patenting grounds, cannot support a double patenting rejection.

(emphasis added).

Accordingly, whether or not the claims of Leahy "read upon" or dominate Fig. 9 of the present application, or are in some aspects broader than the claims of the present application, is irrelevant to the anticipation analysis. Moreover, the claims of Leahy cannot cover what is not disclosed in Leahy, and thus, the claims of Leahy cannot anticipate the claims.

Similarly, the Examiner's comments alleging that statements in the relevant interference proceeding amount to an acknowledgement by the Appellant that the Leahy device "covers the embodiment of Figure 9 of the present application" are also

irrelevant to the anticipation analysis. Office Action, page 14. Along these same lines, Appellant disagrees with the comments in the Office Action alleging that certain statements in the relevant interference proceeding concerning the scope of the claims of Leahy are an acknowledgement that "the claims of Leahy's device can be used without an adhesive." Id. at page 14. Even assuming the statements made during the relevant interference proceeding were to amount to an admission that the scope of certain claims of Leahy were broad enough to cover the device depicted in Fig. 9 of the present application, such statements would in no way imply that the claims disclose the features claimed in independent claim 107 of this application.

For these additional reasons, Appellant submits that independent claim 107 is not anticipated by either the claims or detailed description of the Leahy patent. Accordingly, Appellant requests reversal of the claim rejection. Additionally, the rejection of claims 87-100 that depend from claim 107 should also be reversed for at least the reasons provided above.

c) Leahy does not anticipate claims 87-100 and 107 because Leahy is not prior art under 35 U.S.C. § 102(e)

The following arguments are similar to the arguments presented above with respect to claims 73-85 and 106. The rejection of claims 87-100 and 107 is improper because Leahy is not prior art under 35 U.S.C. § 102(e). Appellant's claims are entitled to the priority date of at least Irish Patent Application No. 930649, filed September 6, 1993 ("the '649 application), under 35 U.S.C. § 119(d). The '649 application lists Frank Bonadio and Patrick Leahy as inventors. Patrick Leahy, however, is not listed as an inventor in the present application. Rather, the present application lists Frank Bonadio

and Alan Reid as inventors. In situations such as this were there is an inconsistency in inventorship between a foreign priority application and a nonprovisional application claiming benefit to the priority application, the PTO suggests that the priority date should be refused until the inconsistency is resolved. See M.P.E.P. § 201.15.

The patent laws of Ireland do not require that the actual inventors be listed initially on an Irish patent application, nor does the inventorship identified initially on an Irish patent application affect the validity of an Irish patent. (See Declaration of Denis McCarthy, Exhibit A). Under Irish patent law, there is a period of 16 months from the filing date of an Irish patent application to provide details of inventorship and derivation of rights. Since the '649 application was only used for priority purposes and was thus abandoned after 12 months, there was no need to conduct an inventorship investigation with respect to the '695 application. Accordingly, an inventorship investigation was not necessary prior to filing the '649 application and any error in the listing of Patrick Leahy as inventor on the '649 application was not legally significant.

Inventorship is resolved by looking to the claims and determining the inventorship for each claims. See 35 U.S.C. § 116. The present application includes independent claim 107 that recites, *inter alia*, "the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment." On page 14 of the Office Action, the Examiner equated claim 107 to one or more of previously pending claims 25-55 and 72-104 from Appellant's Reply to Office Action filed January 5, 2006. Thus, the Declarations of Frank Bonadio and Alan Reid (Exhibits B and C), submitted

with Appellant's Reply to Office Action filed on January 5, 2006, are applicable to claim 107. As explained in the attached Declarations, Frank Bonadio and Alan Reid conceived of this subject matter and Patrick Leahy did not.

Appellant also submits herewith as Exhibit D a final order from an Irish High Court prohibiting Patrick Leahy from representing that he is an inventor of "Dexterity the Amendments and Twist Valve." Dexterity and the Amendments correspond to the subject matter of the '649 application (Exhibit E). This order from the Irish court supports the position that Patrick Leahy is properly omitted as an inventor from the present application.

In view of the above, the inventorship inconsistency between the '649 application and the present application has been satisfactorily explained. Thus, Appellant is entitled to the benefit of the priority date of at least the '649 application. Accordingly, Leahy is not prior art under 35 U.S.C. § 102(e): Leahy was filed on September 2, 1994, while the subject matter of the present application should be accorded the benefit of the September 6, 1993, priority filing date of the '649 application.

Further, contrary to page 5 of the Office Action, the Board of Patent Appeals and Interferences ("BPAI") has not held that as a matter of law, Applicant is not entitled to the priority date of the '649 application. First, to the extent that the withholding of the priority date is based on estoppel, Appellant's showing of non-obviousness over Leahy renders that basis moot. See Office Action, pages 5 and 6; and the Interview Summary mailed April 29, 2008. Second, case law, and in particular, In re Deckler, 977 F.2d 1449 (Fed. Cir. 1992), does not support the withholding of the priority date of the '649 application from Appellant. The sole issue in Deckler was whether the losing party in an

interference proceeding is entitled to a patent covering claims the party admits are patentably indistinguishable from the claim involved in the interference. See Id. at 1450. Appellant, however, is seeking claims that are patentably distinguishable from the claim involved in the interference. Thus, Deckler is inapplicable to the present case. Moreover, Deckler deals with preclusion as to claims, and is silent as to preclusion as to priority under 35 U.S.C. § 119(d).

Furthermore, the BPAI's denial of Appellant's right to the priority date under 35 U.S.C. § 119(d) came in the form of a decision on a preliminary motion. A decision on a preliminary motion in an interference proceeding is not a final judgment for res judicata or estoppel purposes. See Curtis Mfg. Co., Inc. v. Plasti-Clip Corp., 933 F. Supp. 94, 103 (D.N.H. 1995) ("the court finds and rules that the decision reached by the APJ on the parties' preliminary motions in the interference proceeding is not a 'final judgment' as that term is construed for res judicata or collateral estoppel purposes"). For this additional reason, Appellant is not barred from seeking benefit of the priority date of the '649 application, and is entitled to the priority date. Therefore the rejection of the claims under 35 U.S.C. § 102(e) is improper and should be reversed.

D. The rejection under 35 U.S.C. § 102(g) should be reversed

According to M.P.E.P. § 2308.03, there are two main types of interference estoppel:

> [f]irst, a losing party is barred on the merits from seeking a claim that would have been anticipated or rendered obvious by the subject matter of the lost count. *In re Deckler*, 977 F.2d 1449, 24 USPQ2d 1448 (Fed. Cir. 1992); *Ex parte Tytgat*, 225 USPQ 907 (Bd. Pat. App. & Inter. 1985). Second, a losing party is procedurally barred from seeking from the examiner relief that could have been--but was not--sought in the

> interference. 37 CFR 41.127(a)(1); *Ex parte Kimura*, 55 USPQ2d 1537 (Bd. Pat. App. & Inter. 2000) (reissue applicant estopped to claim compound when patentability of that compound could have been put in issue in interference where opponent's application also described compound).

Appellant respectfully requests that the rejection of claims 73-85, 87-100, 106, and 107 be reversed because neither type of interference estoppel is applicable to the present application.

i. The rejection of claims 73-85 and 106 under 35 U.S.C. § 102(g) should be reversed because interference estoppel is inapplicable to the claims

Appellant respectfully requests that the rejection of claims 73-85 and 106 be reversed because neither type of interference estoppel is applicable to the present application.

a) Interference estoppel is inapplicable to claims 73-85 and 106 because the claims are patentably distinct from the sole lost count of Patent Interference No. 104,195

Appellant respectfully submits that with respect to independent claim 106, neither of the two types of interference estoppel applies. First, claim 106 is not anticipated or rendered obvious by the subject matter of the lost count of Patent Interference No. 104,195. Claim 106 recites, *inter alia*,

> an entry seal assembly located proximal the tubular diaphragm, the entry seal assembly configured to maintain a pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment.

Leahy does not teach that increasing the pressure in chamber C will increase engagement of distal ring 14 and tube 13 with abdominal wall L and wound W. This is

due to the coupling of surgical apparatus 10 of Leahy to the top of abdominal wall L using flange 26 and adhesive 28. As long as flange 26 is adhered to the top of abdominal wall L, increasing pressure in chamber C will not urge tube 13 and ring 14 relative to wound W and abdominal wall L to increase their engagement with wound W and abdominal wall L. Thus, adhesive couplings, like those in Leahy, fail to utilize the insufflation pressure to assist in coupling the device to the patient. Rather, such adhesive couplings work against the insufflation pressure by tending to separate or detach at increased pressures.

The increase in engagement with increasing pressure, described in independent claim 106, provides numerous advantages that are not disclosed or recognized in Leahy. For example, in the present application, increasing the engagement of tubular diaphragm 62 and distal ring 63 with the incision and body tissue 30 using an increase in pressure allows coupling of surgical device 60 to the patient without requiring the use of adhesive. In contrast, a device that relies on adhesive coupling, such as surgical apparatus 10 of Leahy, to secure the device to a patient outside the body would not necessarily stretch or tension the material extending out from inside the body, and thus would require appropriate sizing to match the thickness of the patient's skin to assure that a distal end of the material does not dangle within the patient's body. Accordingly, devices that utilize adhesives to couple the device to a patient outside the body would need to be separately sized for the many different skin thicknesses of patients to avoid excess material from extending into the body. This drawback is present in Leahy. See Leahy, column 4, lines 48-59. For at least the above reasons, independent claim 106 is novel and non-obvious over Leahy. Accordingly, the first type of interference estoppel

does not apply to claim 106. See M.P.E.P. § 2308.03. Appellant submits that the first type of interference estoppel does not apply to claims 73-85, which depend from claim 106, for at least the same reasons that the first type of interference estoppel is inapplicable to claim 106.

b) Interference estoppel is inapplicable to claims 73-85 and 106 because Appellant could not have properly moved to add a count to Patent Interference No. 104,195 corresponding to independent claim 106

Second, 37 C.F.R. § 41.127(a)(1) states that a losing party to an interference who could have properly moved, but failed to move, shall be estopped to take actions in the Patent Office inconsistent with the failure to properly move. See M.P.E.P § 2308.03. For example, 37 C.F.R. § 41.121 may permit a motion in an interference proceeding to redefine the interfering subject matter by adding or substituting a count. Application of these and other relevant rules to the present case indicates that estoppel will not apply to the claims of the present application if: (1) Leahy could not support the claims of the present application or add such claims, and (2) the claims of the present application are directed to a separate patentable invention from the count. As will be explained in detail below, the claims of the present application are not supported by the disclosure of Leahy, could not be added nonetheless because Leahy was a granted patent at the time of the interference, and lastly, define a separate patentable invention over the claims/count of Leahy.

For the same reasons provided above that the claims and detailed description of Leahy do not anticipate the claims of the present application, the claims of the present application are not supported anywhere by the Leahy disclosure and the claims of the

present application are directed to a separate patentable invention from the count. Accordingly, Appellant could not have moved to add a count to the earlier interference proceeding directed to the invention of the pending claims of this application. And, even assuming *arguendo* the Leahy disclosure did support such claims, Leahy could not be amended during the interference because it was a granted patent at the time of the interference. Thus, because Appellant could not have moved to add a count to the earlier interference corresponding to independent claim 106, Appellant is not seeking from the Examiner relief that could have been sought in the interference. For at least this reason, the second type of interference estoppel does not apply, and the rejection of claim 106 under 35. U.S.C. § 102(g) is improper and should be reversed. See M.P.E.P. § 2308.08.

Appellant submits that the 35 U.S.C. § 102(g) rejection of claims 73-85, which depend from independent claim 106, should be reversed for at least the same reasons that the 35 U.S.C. § 102(g) rejection of claim 106 should be reversed. In addition, the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore are also separately patentably distinct.

ii. The rejection of claims 87-100 and 107 under 35 U.S.C. § 102(g) should be reversed because interference estoppel is inapplicable to the claims

Appellant respectfully requests that the rejection of claims 87-100 and 107 be reversed because neither type of interference estoppel is applicable to the present application. The following arguments are similar to those presented above with respect to the rejection of claims 73-85 and 106 under 35 U.S.C. § 102(g).

a) Interference estoppel is inapplicable to claims 87-100 and 107 because the claims are patentably distinct from the sole lost count of Patent Interference No. 104,195

Appellant respectfully submits that with respect to independent claim 107, neither of the two types of interference estoppel applies. First, claim 107 is not anticipated or rendered obvious by the subject matter of the lost count of Patent Interference No. 104,195. Claim 107 recites, *inter alia*,

> the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment.

Leahy discloses that flange 26 and adhesive 28 form the first sealing means. See Leahy, column 3, lines 60-67. This suggests that flange 26 of Leahy acts as a boundary structure having a first side (below flange 26 in FIG. 3) subject to the same pressure as the pressurized gas in cavity A, and a second side (above flange 26 and outside of sleeve 18 in FIG. 3) subject to atmospheric pressure. Since both the wound engaging portion of tube 13 and the internal portion of tube 13 are on the first side of the boundary (below flange 26 in FIG. 3), they are both subject to the pressure associated with the pressurized gas in cavity A.

Applicant's claimed arrangement of having the internal portion of tubular diaphragm 62 subject to the controlled pressurized environment, while having the wound engaging portion of tubular diaphragm 62 not subject to the controlled pressurized environment, provides numerous advantages that are not disclosed or recognized in Leahy. The arrangement allows distal ring 63 and diaphragm 62 to together form the only coupling with the patient's body. As such, the use of an adhesive

to maintain coupling to the patient is entirely avoided, along with the drawbacks associated with using adhesive (discussed above with respect to independent claim 106). Additionally, the arrangement provides advantages in terms of coupling and ability to adapt to different skin thicknesses (also discussed above with respect to claim 106). For at least the above reasons, independent claim 107 is novel and non-obvious over Leahy. Accordingly, the first type of interference estoppel does not apply to claim 107. See M.P.E.P. § 2308.03. Appellant submits that the first type of interference estoppel does not apply to claims 87-100, which depend from claim 107, for at least the same reasons that the first type of interference estoppel is inapplicable to claim 107.

b) Interference estoppel is inapplicable to claims 87-100 and 107 because Appellant could not have properly moved to add a count to Patent Interference No. 104,195 corresponding to independent claim 107

Second, 37 C.F.R. § 41.127(a)(1) states that a losing party to an interference who could have properly moved, but failed to move, shall be estopped to take actions in the Patent Office inconsistent with the failure to properly move. See M.P.E.P § 2308.03. For example, 37 C.F.R. § 41.121 may permit a motion in an interference proceeding to redefine the interfering subject matter by adding or substituting a count. Application of these and other relevant rules to the present case indicates that estoppel will not apply to the claims of the present application if: (1) Leahy could not support the claims of the present application or add such claims, and (2) the claims of the present application are directed to a separate patentable invention from the count. As will be explained in detail below, the claims of the present application are not supported by the

disclosure of Leahy, could not be added nonetheless because Leahy was a granted patent at the time of the interference, and lastly, define a separate patentable invention over the claims/count of Leahy.

For the same reasons provided above that the claims and detailed description of Leahy do not anticipate the claims of the present application, the claims of the present application are not supported anywhere by the Leahy disclosure and the claims of the present application are directed to a separate patentable invention from the count. Accordingly, Appellant could not have moved to add a count to the earlier interference proceeding directed to the invention of the pending claims of this application. And, even assuming *arguendo* the Leahy disclosure did support such claims, Leahy could not be amended during the interference because it was a granted patent at the time of the interference. Thus, because Appellant could not have moved to add a count to the earlier interference corresponding to independent claim 107, Appellant is not seeking from the Examiner relief that could have been sought in the interference. For at least this reason, the second type of interference estoppel does not apply, and the rejection of claim 107 under 35. U.S.C. § 102(g) should be reversed. See M.P.E.P. § 2308.08.

Appellant submits that the 35 U.S.C. § 102(g) rejection of claims 87-100, which depend from independent claim 107, should be reversed for at least the same reasons that the 35 U.S.C. § 102(g) rejection of claim 107 should be reversed. In addition, the dependent claims recite unique combinations that are neither taught nor suggested by the cited art, and therefore are also separately patentably distinct.

VIII. CONCLUSION

For the reasons given above, pending claims 73-85, 87-100, 106, and 107 are in compliance with 35 U.S.C. § 112, first paragraph; are novel and non-obvious over Leahy; and are not barred by interference estoppel. The Board is therefore requested to reverse all of the claim rejections under 35 U.S.C. § 112, first paragraph, 35 U.S.C. § 102(e), and 35 U.S.C. § 102(g), so that all of pending claims 73-85, 87-100, 106, and 107 may be allowed.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 4, 2009

By: 

Thomas Y. Ho
Reg. No. 61,539
(202) 408-4000

IX. CLAIMS APPENDIX TO APPEAL BRIEF UNDER RULE 41.37(C)(1)(VIII)

1-72. (Cancelled).

73. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly is configured to receive and seal at least part of a human arm.

74. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly is configured to receive and seal at least part of an instrument.

75. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly is movable between an unsealed configuration and a sealed configuration, and the entry seal assembly includes a locking assembly configured to secure the entry seal assembly in the sealed configuration.

76. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly includes a first component and a second component, the first component being completely detachable from the second component.

77. (Previously Presented) A surgical device as claimed in claim 76, wherein the first component includes a surgical glove.

78. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly includes a first member and a second member connected together by a sleeve member, the first and second members being rotatable relative to one another to seal an object.

79. (Previously Presented) A surgical device as claimed in claim 78, wherein the first member includes a first ring, and the second member includes a second ring.

80. (Previously Presented) A surgical device as claimed in claim 79, wherein the first ring includes a circular shape, and the second ring includes a circular shape.

81. (Previously Presented) A surgical device as claimed in claim 79, wherein the entry seal assembly includes a locking assembly configured to secure the first and second rings together.

82. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly includes a sleeve extending between a seal mechanism and a proximal ring.

83. (Previously Presented) A surgical device as claimed in claim 82, wherein the proximal ring includes a circular shape, and the distal ring includes a circular shape.

84. (Previously Presented) A surgical device as claimed in claim 83, wherein the proximal ring, distal ring, and diaphragm have approximately the same inner diameter.

85. (Previously Presented) A surgical device as claimed in claim 106, wherein the entry seal assembly forms a proximal-most portion of the surgical device.

86. (Cancelled).

87. (Previously Presented) A surgical device as claimed in claim 107, wherein the entry seal assembly is configured to receive and seal at least part of a human arm.

88. (Previously Presented) A surgical device as claimed in claim 107, wherein the entry seal assembly is configured to receive and seal at least part of an instrument.

89. (Previously Presented) A surgical device as claimed in claim 107, wherein the entry seal assembly is movable between an unsealed configuration and a sealed configuration, and the entry seal assembly includes a locking assembly configured to secure the entry seal assembly in the sealed configuration.

90. (Previously Presented) A surgical device as claimed in claim 107, wherein the entry seal assembly includes a first component and a second component, the first component being completely detachable from the second component.

91. (Previously Presented) A surgical device as claimed in claim 90, wherein the first component includes a surgical glove.

92. (Previously Presented) A surgical device as claimed in clam 107, wherein the entry seal assembly includes a first member and a second member connected together by a sleeve member, the first and second members being rotatable relative to one another to seal an object.

93. (Previously Presented) A surgical device as claimed in claim 92, wherein the first member includes a first ring, and the second member includes a second ring.

94. (Previously Presented) A surgical device as claimed in claim 93, wherein the first ring includes a circular shape, and the second ring includes a circular shape.

95. (Previously Presented) A surgical device as claimed in claim 93, wherein the entry seal assembly includes a locking assembly configured to secure the first and second rings together.

96. (Previously Presented) A surgical device as claimed in claim 107, wherein the entry seal assembly includes a sleeve extending between a seal mechanism and a proximal ring.

97. (Previously Presented) A surgical device as claimed in claim 96, wherein the proximal ring includes a circular shape, and the distal ring includes a circular shape.

98. (Previously Presented) A surgical device as claimed in claim 97, wherein the proximal ring, distal ring, and diaphragm have approximately the same inner diameter.

99. (Previously Presented) A surgical device as claimed in claim 107, wherein the entry seal assembly forms a proximal-most portion of the surgical device.

100. (Previously Presented) A surgical device as claimed in claim 107, wherein the distal ring is larger than the incision.

101-105. (Cancelled).

106. (Previously Presented) A surgical device providing sealed access through an incision in a patient, the device comprising:

a distal ring insertable through the incision to engage internal body tissue;

a tubular diaphragm having a distal end, a proximal end, and an incision engaging portion,

the distal end of the tubular diaphragm being coupled to the distal ring,

the incision engaging portion configured to engage the incision, and

the proximal end of the tubular diaphragm located proximal the distal ring and outside the incision; and

an entry seal assembly located proximal the tubular diaphragm,

the entry seal assembly configured to maintain a controlled pressurized environment inside the surgical device such that the engagement of the incision engaging portion of the diaphragm with the incision and engagement of the distal ring to the internal body tissue increases with an increase in pressure within the controlled pressurized environment.

107. (Previously Presented) A surgical device providing sealed access through an incision in a patient, the device comprising:

a distal ring insertable through the incision to engage internal body tissue;

a tubular diaphragm having a distal end, a proximal end, an internal portion, and an incision engaging portion opposite the internal portion,

the distal end of the tubular diaphragm being coupled to the distal ring and the proximal end of the tubular diaphragm located proximal the distal ring and outside the incision; and

an entry seal assembly located proximal the tubular diaphragm and configured to maintain a controlled pressurized environment inside the surgical device,

the engagement of the distal ring to the internal body tissue providing a seal such that the incision engaging portion of the tubular diaphragm is not subject to the controlled pressurized environment, while the internal portion of the tubular diaphragm is subject to the controlled pressurized environment.

108-110. (Cancelled).

X. EVIDENCE APPENDIX TO APPEAL BRIEF UNDER RULE 41.37(C)(1)(IX)

The exhibits attached to this Evidence Appendix including the following:

Exhibit A: Declaration of Denis McCarthy (submitted as an attachment to the Reply to Office Action filed January 5, 2006).

Exhibit B: Declaration of Alan Reid (submitted as an attachment to the Reply to Office Action filed January 5, 2006).

Exhibit C: Declaration of Frank Bonadio (submitted as an attachment to the Reply to Office Action filed January 5, 2006).

Exhibit D: Order from Irish High Court (submitted as an attachment to the Reply to Office Action filed January 5, 2006).

Exhibit E: Copy of Irish Patent Application No. 930649 (submitted as an attachment to the Reply to Office Action filed January 5, 2006.

XI. RELATED PROCEEDINGS APPENDIX TO APPEAL BRIEF UNDER RULE 41.37(C)(1)(X)

The Exhibit attached to this Appendix includes the following:

Exhibit F: Copy of the Judgment in Patent Interference No. 104,195.

EXHIBIT A

PATENT
Customer No. 22,852
Attorney Docket No. 08203-0030-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Frank BONADIO et al.	Group Art Unit: 3743
Application No.: 10/600,812	Examiner: Dinnatia DOSTER GREENE
Filed: June 20, 2003	Confirmation No. 7588
For: APPARATUS FOR USE IN SURGERY AND A VALVE	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF DENIS MCCARTHY

I, Denis McCarthy, a citizen of Ireland, declare as follows:

1. I am making this Declaration in support of obtaining benefit of the filing date of Irish Patent Application No. 930649 ("the '649 application") in the above-referenced application ("the Bonadio application") in accordance with 35 U.S.C. § 119(d). I understand that this Declaration will be filed in the United States Patent & Trademark Office in the Bonadio application.

2. I am a registered Irish patent agent and European patent attorney with over 25 years of experience prosecuting patent applications before the Irish Patents Office.

3. The patent laws of Ireland do not (and did not at the time the '649 application was filed in September 1993) require that the actual inventors be listed

initially on an Irish patent application. Under Irish patent law, there is a period of 16 months from the filing date of an Irish patent application to provide details of inventorship and derivation of rights. Since the '649 application was only used for priority purposes and was thus abandoned after 12 months, there would have been no need to conduct an inventorship investigation with respect to the '649 application.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: January 3, 2006

By: Denis Mc Carthy
Denis McCarthy

EXHIBIT B

PATENT
Customer No. 22,852
Attorney Docket No. 08203-0030-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
Frank BONADIO et al.	)	Group Art Unit: 3743
Application No.: 10/600,812	)	Examiner: Dinnatia DOSTER GREENE
Filed: June 20, 2003	)	Confirmation No. 7588
For: APPARATUS FOR USE IN SURGERY AND A VALVE	)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF ALAN REID

I, Alan Reid, a citizen of Ireland, declare as follows:

1. I am making this Declaration in support of obtaining benefit of the filing date of Irish Patent Application No. 930,649 ("the '649 application") in the above-referenced application ("the Bonadio application") in accordance with 35 U.S.C. § 119(d). I understand that this Declaration will be filed in the United States Patent & Trademark Office in the Bonadio application.

2. I have reviewed the subject matter disclosed and claimed in the Bonadio application.

3. It is my understanding that under United States patent laws an individual is properly designated as an inventor on a U.S. patent or patent application provided the

individual is an inventor (joint or sole) of the subject matter of at least one claim. Based on this standard, I am properly designated as an inventor of the Bonadio application.

4. My contributions to the subject matter of the Bonadio application include, among other things, certain concepts recited in at least independent claims 25, 41, 72, and 86, and the entry seal assembly depicted in Figs. 5-7 of the Bonadio application. Accordingly, I believe that I am an inventor of certain subject matter of at least claims 25, 31-34, 41, 47-50, 72, 78-81, 86, and 92-95 of the Bonadio application, as these claims exist in the Reply to Office Action filed herewith.

5. I further believe that Frank Bonadio is properly designated as an inventor of the Bonadio application. Frank Bonadio's contributions include, among other things, certain concepts recited in at least independent claims 25, 41, 72, and 86 of the Bonadio application, as these claims exist in the Reply to Office Action filed herewith.

6. I have also reviewed the '649 application, titled "Apparatus for Use in a Surgery," filed September 6, 1993.

7. I am an inventor of certain subject matter disclosed in the '649 application. My contributions to the '649 application include, among other things, certain aspects of the patient coupling assembly depicted in Fig. 9, and of the entry seal assembly depicted in Figs. 5-7 of the '649 application.

8. I further believe that Frank Bonadio is an inventor of certain subject matter of the '649 application. Frank Bonadio's contributions to the '649 application include, among other things, certain aspects of the patient coupling assembly depicted in Fig. 9 of the '649 application.

9. I do not believe that Patrick Leahy is an inventor of the subject matter disclosed and/or claimed in the Bonadio application. Accordingly, I also do not believe that Patrick Leahy was an inventor of any subject matter of the '649 application that supports the claims of the Bonadio application, as these claims exist in the Reply to Office Action filed herewith.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 30/12/05 By: 
Alan Reid

EXHIBIT C

PATENT
Customer No. 22,852
Attorney Docket No. 08203-0030-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	
Frank BONADIO et al.	Group Art Unit: 3743
Application No.: 10/600,812	Examiner: Dinnatia DOSTER GREENE
Filed: June 20, 2003	Confirmation No. 7588
For: APPARATUS FOR USE IN SURGERY AND A VALVE	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION OF FRANK BONADIO

I, Frank Bonadio, a citizen of the United States, declare as follows:

1. I am making this Declaration in support of obtaining benefit of the filing date of Irish Patent Application No. 930,649 ("the '649 application") in the above-referenced application ("the Bonadio application") in accordance with 35 U.S.C. § 119(d). I understand that this Declaration will be filed in the United States Patent & Trademark Office in the Bonadio application.

2. I have reviewed the subject matter disclosed and claimed in the Bonadio application.

3. It is my understanding that under United States patent laws, an individual is properly designated as an inventor on a U.S. patent or patent application provided the

individual is an inventor (joint or sole) of the subject matter of at least one claim. Based on this standard, I am properly designated as an inventor of the Bonadio application.

4. My contributions to the subject matter of the Bonadio application include, among other things, certain concepts recited in at least independent claims 25, 41, 72, and 86 of the Bonadio application, as these claims exist in the Reply to Office Action filed herewith.

5. I further believe that Alan Reid is properly designated as an inventor of the Bonadio application. Alan Reid's contributions include, among other things, certain concepts recited in at least independent claims 25, 41, 72, and 86, and the entry seal assembly depicted in Figs. 5-7 of the Bonadio application. Thus, I believe that Alan Reid is an inventor of certain subject matter of at least claims 25, 31-34, 41, 47-50, 72, 78-81, 86, and 92-95 of the Bonadio application, as these claims exist in the Reply to Office Action filed herewith.

6. I have also reviewed the '649 application, titled "Apparatus for Use in a Surgery," filed September 6, 1993.

7. I am an inventor of the subject matter disclosed in the '649 application. My contributions to the '649 application include, among other things, certain aspects of the patient coupling assembly depicted in Fig. 9 of the '649 application.

8. I further believe that Alan Reid is an inventor of certain subject matter of the '649 application. Alan Reid's contributions to the '649 application include, among other things, certain aspects of the patient coupling assembly depicted in Fig. 9, and the entry seal assembly depicted in Figs. 5-7 of the '649 application.

9. I do not believe that Patrick Leahy is an inventor of the subject matter disclosed and/or claimed in the Bonadio application. Accordingly, I also do not believe that Patrick Leahy was an inventor of the subject matter of the '649 application that supports the claims of the Bonadio application, as these claims exist in the Reply to Office Action filed herewith.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: December 29 '05 By: _____
Frank Bonadio

EXHIBIT D

G.1.

THE HIGH COURT

1995 No 1074p

Monday the 23rd day of March 1998

BEFORE MR JUSTICE KELLY

BETWEEN

FRANK BONADIO AND ENCORET LIMITED

PLAINTIFFS

AND

PATRICK LEAHY AND BJORG CORPORATION LIMITED

DEFENDANTS

The Plaintiffs' Notion of Motion herein dated the 23rd day of January 1998 being called on for hearing on this day in the presence of Counsel for the Plaintiffs there being no appearance by or on behalf of the Defendants

On reading the said Notice of Motion the Master's Order herein dated the 26th June 1997 the Affidavit of Mary Flynn sworn on the 22nd day of January 1998 and on hearing said Counsel

IT IS ORDERED that the first and/or second named Defendant(s) their servants and agents or otherwise howsoever be permanently restrained and prohibited from stating and representing to any party that the first named Defendant herein is or was the sole inventor or an inventor of Dexterity the Amendments and Twist Valve

The Court doth declare that the first named Plaintiff is the sole inventor of Dexterity the Amendments and Twist Valve but that by virtue of an agreement made between the first named Plaintiff and the first named Defendant both are entitled to be registered as joint inventors of Dexterity the Amendments and Twist Valve

The Court doth declare that the first named Plaintiff and the first named Defendant are entitled to share equally in the profits derived from the use and exploitation of Dexterity the Amendments and Twist Valve by virtue of an agreement made between the said first named Plaintiff and the first named Defendant in relation thereto

IT IS ORDERED that the first and/or second named Defendant(s) their servants and agents or otherwise howsoever be permanently restrained and prohibited from registering patents and/or making patent filings in respect of Dexterity the Amendments and Twist Valve in any jurisdiction save only with the consent of the first and/or second named Plaintiff(s) herein and subject to the said registration and/or patent filing recording the fact that the first named Plaintiff herein was the inventor of the said Dexterity the Amendments and Twist Valve

IT IS ORDERED that the first and/or second named Defendants their servants and/or agents or otherwise however be permanently restrained and prohibited from registering patents and/or making patent filings which infringe incorporate or otherwise use Dexterity and/or the Amendments and/or Twist Valve

IT IS ORDERED that the first and/or second named Defendant(s) their servants and agents or otherwise howsoever be permanently restrained and prohibited from entering into any agreements for the manufacture and/or distribution of Dexterity the Amendments and Twist Valve and from entering into any licensing agreements in connection therewith save with the consent of the first or second named Plaintiff herein

The Court doth declare that the first named Plaintiff was and is entitled to ownership of 50% of the shareholding in the second named Defendant Company

THE HIGH COURT

The Court doth declare that 50% of the shareholding of the second named Defendant is held on trust for the use and benefit of the Plaintiffs

IT IS ORDERED that the first and/or second named Defendants do procure the transfer and/or allotment of shares and registration of the first named Plaintiff as a shareholder in respect of 50% of the shareholding of the second named Defendant Company

IT IS ORDERED that the first named Defendant and second named Defendant Company its servants and agents be permanently restrained and prohibited from taking any steps so as to alter or otherwise dilute the first named Plaintiff's shareholding in the second named Defendant Company

IT IS ORDERED AND ADJUDGED that the Plaintiffs do recover against the Defendants such amount as the Court may assess in respect of the Plaintiffs' claim herein for damages for breach of contract breach of trust and fiduciary duty breach of duty and for infringement of any patent granted or to be granted in respect of Dexterity and/or Amendments and/or Twist Valve or any invention embodying them and the costs of suit on taxation such costs to include the costs of this Motion and of the assessment and that such assessment be had before a Judge only and be set down for hearing accordingly

Liberty to apply in respect of (d) in the Plaintiffs' Statement of Claim

REGISTRAR

A Copy ...

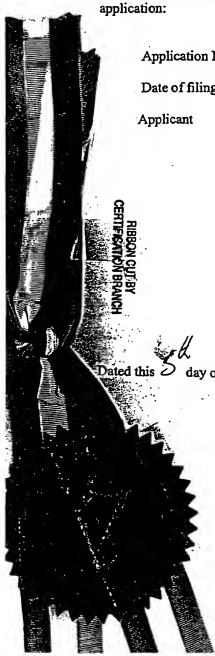
Sup ...

Binchys
Solicitors for Plaintiffs

EXHIBIT E

Patents Office
45 Merrion Square
Dublin 2

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:



Application No.	930649
Date of filing	6 September 1993
Applicant	PATRICK LEAHY an Irish citizen, of Apartment 9, The Elms, Mount Merrion Avenue, Blackrock, County Dublin, Ireland, and FRANK BONADIO a U.S. citizen, of 2 Martello Terrace, Bray, County Wicklow, Ireland.

Dated this 5th day of June, 1998

An officer authorised by the
Controller of Patents, Designs and Trademarks.

FORM NO. 1

930[redacted]

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

[X] the grant of a patent under Part II of the Act

[ ] the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name 1. PATRICK LEAHY

2. FRANK BONADIO

Address

Apartment 9, The Elms,
Mount Merrion Avenue,
Blackrock, County Dublin, Ireland.

2 Martello Terrace,
Bray,
County Wicklow,
Ireland.

Description/Nationality

an Irish Citizen

a U.S. Citizen

2. Title of Invention

"Apparatus for use in surgery"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

PATRICK LEAHY,
an Irish Citizen

Frank Bonadio,
a U.S. Citizen of

Address

Apartment 9,
The Elms,
Mount Merrion Avenue,
Blackrock,
County Dublin,
Ireland.

2 Martello Terrace,
Bray,
County Wicklow,
Ireland.

CONTINUED OVER

5. Statement of right to be granted a patent (Section 17(2)(b))

Not Applicable

6. Items accompanying this Request - tick as appropriate

(i) [x] prescribed filing fee (£117)

(ii) [x] specification containing a description and claims

[ ] specification containing a description only

[x] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [x] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No: .....
Filing Date: .....

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name	Address
CRUICKSHANK & CO.,	1 Holles Street, Dublin 2, Ireland.

9. Address for Service (if different from that at 8)

CRUICKSHANK & CO., at their address recorded for the time being in the Register of Patent Agents is hereby appointed Agents and address for service.

Signed ..... Name(s): CRUICKSHANK & CO.,
BY [signature] EXECUTIVE
Capacity (if applicant is a body corporate):
Agents for the Applicant

Date September 6, 1993

"Apparatus for Use in Surgery"

The invention relates to an apparatus for use in surgery and in particular to an apparatus to be used in minimal invasive surgery in which surgery is carried out by making the minimum number of incisions in a patient's body.

Abdominal surgery is generally carried out by making a very large incision allowing a surgeon to enter the body cavity with both hands. Such surgery is traumatic for the patient and the healing process is lengthy. Some laproscopic surgery such as hernia operations may be carried out by surgeons using minimal invasive techniques with trocar assemblies. However, the techniques are generally complex and difficult and are not widely used.

According to the invention there is provided an apparatus for use in surgery comprising a sleeve having an entry opening at an outer end thereof and an exit opening at an inner end thereof to access a patient's body, exit sealing means being provided for sealing the exit opening to a body and entry sealing means being provided for sealing the outer entry gainst an arm passing therethrough to create a controlled environment within the sleeve.

In a particularly preferred embodiment of the invention the sleeve is of a flexible material. Most preferably, the sleeve is of a gas-impermeable material to create a controlled pressurised environment within the sleeve.

In a particularly preferred embodiment of the invention the sleeve comprises a generally cylindrical body closed at one end thereof and an exit opening is provided in a side wall of a body adjacent the closed end.

In one arrangement the exit sealing means comprises a flange around the exit for sealing against the body of a patient. Preferably the flange is provided with an adhesive for adhering to the body. Typically the exit and flange are covered by a peel-off cover.

In another arrangement the flange is engaged with a mounting ring surrounding an incision in a patient's body.

The entry sealing means may comprise a valve means through which a surgeon passes an arm. Preferably the valve means is of a material which is sufficiently flexible to allow an arm to be passed therethrough and to seal against the arm when passed therethrough.

Alternatively, the means comprises a first mounting in the sleeve entry, a second mounting and a sealing body of flexible material extending between the mountings, one of the mountings being twisted relative to the other two to twist the sealing body into engagement with an arm passing therethrough.

In one arrangement fixing means are provided for fixing one mounting relative to the other in the sealing position. Typically the fixing means comprises inter-engaging formations provided on the mountings.

In another arrangement the first mounting comprises a ring mounted in the sleeve at the entry thereof.

In a particularly preferred arrangement the second mounting comprises a ring to which the sealing material is attached.

In one embodiment of the invention the entry sealing means comprises a first sealing element provided in the entry

and a second sealing entry provided on a surgical glove, the sealing elements inter-engaging to seal the sleeve on passing of the glove through the entry.

The invention will be more clearly understood from the following description thereof, given by way of example only with reference to the accompanying drawings in which:-

Fig. 1 is a plan view of a sleeve;

Fig. 2 is a cross-sectional view of the sleeve of Fig. 1;

Fig. 3 is a plan view of a sleeve with an entry sealing means in position;

Fig. 4 is a perspective view of the sleeve of Fig. 3 in use;

Fig. 5 is a perspective view of the entry sealing means used in the sleeve of Figs. 3 and 4 in an open configuration;

Fig. 6 is a side elevational view of the sealing means of Fig. 5 in an intermediate position;

Fig. 7 is a perspective view of the sealing means of Fig. 5 in a sealed configuration;

Fig. 8 is a perspective view of another sleeve according to the invention; and

Fig. 9 is a side cross-sectional view of a further sleeve according to the invention.

Referring to the drawings and initially to Figs. 1 to 7 thereof, there is illustrated an apparatus for use in surgery according to the invention indicated generally by the reference numeral 1. The apparatus 1 comprises a sleeve 2 of flexible gas-impermeable material. The sleeve 2 in this case comprises a generally cylindrical body closed at one end 3 thereof and open at the other end 4 thereof to define an entry opening at an outer end for passage of an instrument and/or surgeon's arm. An exit opening 5 is provided in a side wall of the sleeve 2 as illustrated particularly in Fig. 2 to provide an access point for entering a patient's body through an incision therein.

Exit sealing means 10 for sealing the exit opening 5 to a patient's body is in this case provided by a flange 11 around the exit opening 5 to the outer face of which is applied a pressure sensitive adhesive for adhering to the body of the patient. The adhesive side of the flange 11 is covered prior to use with a peel-off cover 12.

Entry sealing means which for clarity is not illustrated in Figs. 1 and 2 is in this case provided by a valve means indicated generally by the reference numeral 20 and illustrated particularly in Figs. 3 to 7. The valve means 20 comprises a first mounting provided by a ring 21 attached to the body of the sleeve 2 at the entry 4 and a second mounting provided by another ring 22 which is attached to the first ring 21 by a sealing member 23 of flexible material extending between the rings.

The outer ring 22 with the flexible body 23 attached is rotated to twist the sealing body 23 in the direction of the arrow X illustrated in Fig. 6 to engage and seal against a surgeon's arm 30 passing therethrough. When the sealing member 23 is in sealing engagement the outer ring

22 is pushed forwardly in the direction of the arrow Y against the inner ring 21 and the rings are engaged together to maintain the sealing engagement.

Fixing means for preventing rotation of the rings 21, 22 relative to one another when the rings are in the sealing position illustrated in Fig. 7 is in this case provided by a plurality of projections 27 on one of the rings 22 which are engageable with a plurality of complimentary shaped recesses 28 in the other rings 21 to lock the rings 21,22 against rotation in the sealing position.

In use, an incision is first made in a patient 31. The cover 11 is then removed and the flange 12 is adhesively bonded to the patient around the incision as illustrated particularly in Fig. 4. The sleeve is arranged so that the exit opening 5 is aligned with the incision in the patient 31. With the entry sealing means 20 in the open non-sealing configuration illustrated in Figs. 3 and 5 a surgeon passes his hand and arm 30 through the entry 4 and the exit opening 5 to enter the patient's body through the incision. When the surgeon's arm 30 has passed through the sealing means 20 a desired distance, the outer ring 22 with the sealing body 23 attached is rotated to twist the sealing body 23 to engage against the surgeon's arm 30 until a relatively tight seal is obtained. The ring 22 is then pushed forwardly against the ring 21 and the projections are engaged in the recesses 28 to lock the rings 21, 22 together against rotation in the sealing configuration. In the case of bowel re-section surgery, gas is pumped into the patient's body cavity where the surgery is to be performed, the gas exiting through the incision in the patient and the opening 5 into the sleeve 2 to create a controlled pressurised environment in the sleeve 2 in which the sleeve 2 is inflated. The surgeon carries out the surgery as required and when completed the

ring 22 is released from the ring 21 and contra-rotated until the flexible body 23 is in the non sealing position allowing the surgeon to extract his hand through the sleeve 2.

There are many advantages of the invention. Because a surgeon need only make a relatively small incision the trauma to the patient is minimised, there is less risk of damage to the immune system and the healing time is short with a consequent decrease in the length of the hospital stay required. The techniques are considerably simpler than conventional laproscopic surgical techniques and can be readily performed by a surgeon with minimal additional training. A wide range of operations can be performed using the apparatus of the invention.

Referring to Fig. 8 there is illustrated another apparatus for use in surgery according to the invention indicated generally by the reference numeral 50. The apparatus 50 is similar to the apparatus described above with reference to Figs. 1 to 4 and like parts are assigned the same reference numerals. In this case the entry sealing means comprises a first ring 51 mounted to the sleeve 2 at the entry 4 and a second separate ring 52 at the free end of a surgical glove 53. When a surgeon's arm with the glove 53 passes through the entry 5 the rings 51, 52 are arranged to sealingly engage to create a controlled environment within the sleeve 2 during an operation.

Referring to Fig. 9 there is illustrated a further apparatus according to the invention for use in surgery and indicated generally by the reference numeral 60. In this case, the exit sealing means comprises a sealing diaphragm having a first ring 61 attached to the sleeve 2 and a flexible diaphragm 62 extending from the ring 61 and terminating in an inner ring 63 which is inserted

through the incision to engage with the body tissue 30 as illustrated. The sealing diaphragm seals the exit 5 of the sleeve 2 to the incision in the patient's body to create a controlled pressurised environment in the sleeve 2.

It is anticipated that in some cases adhesive may be applied to a patient around the area of an incision to which a sealing ring of the sleeve is to be attached during preparations for an operation. Adhesive may alternatively or additionally be applied to the ring to be attached around the area of an incision. Either or both layers of adhesive may be covered by a sterile wrapping material through which the incision may be made. Either or both layers of adhesive may be provided with peel off covers.

It will further be appreciated that the sleeve may incorporate an air lock to facilitate changing of an instrument and/or debris such as cancer cells during an operation without breaking the sterilised environment in the sleeve.

The sleeve may be provided with more than one inlet opening for a surgeon's arms and/or instruments.

The sleeve may also be provided with means to create an intermediate pressurised environment by, for example, providing two inlet sealing cuffs spaced-apart along the sleeve. The inner of the cuffs being sealed before the seal provided by the outer cuff is opened.

Many variations on the specific embodiments of the invention described will be readily apparent and accordingly the invention is not limited to the embodiments hereinbefore described, but may be varied in construction and detail.

CLAIMS:

1. Apparatus for use in surgery comprising a sleeve having an entry opening at an outer end thereof and an exit opening at an inner end thereof to access a patient's body, exit sealing means being provided for sealing the exit opening to a body and entry sealing means being provided for sealing the outer entry against an arm passing therethrough to create a controlled environment within the sleeve.

2. Apparatus as claimed in Claim 1 wherein the sleeve is of a flexible material.

3. Apparatus as claimed in Claim 1 or 2 wherein the sleeve is of a gas-impermeable material to create controlled pressurised environment within the sleeve.

4. Apparatus as claimed in any preceding claim wherein the sleeve comprises a generally cylindrical body closed at one end thereof and an exit opening is provided in a side wall of a body adjacent the closed end.

5. Apparatus as claimed in any preceding claim wherein the exit sealing means comprises a flange around the exit for sealing against the body of a patient.

6. Apparatus as claimed in Claim 5 wherein the flange is provided with an adhesive for adhering to the body.

7. Apparatus as claimed in Claim 5 or 6 wherein the exit and flange are covered by a peel-off cover.

8. Apparatus as claimed in Claim 5 wherein the flange is engaged with a mounting ring surrounding an incision in a patient's body.

9. Apparatus as claimed in any preceding claim wherein the entry sealing means comprises a valve means through which a surgeon passes an arm.

10. Apparatus as claimed in Claim 9 wherein the valve means is of a material which is sufficiently flexible to allow an arm to be passed therethrough and to seal against the arm when passed therethrough.

11. Apparatus as claimed in Claim 9 wherein the valve means comprises a first mounting in the sleeve entry, a second mounting and a sealing body of flexible material extending between the mountings, one of the mountings being twisted relative to the other to twist the sealing body into engagement with an arm passing therethrough.

12. Apparatus as claimed in Claim 11 wherein fixing means are provided for fixing one mounting relative to the other in the sealing position.

13. Apparatus as claimed in Claim 12 wherein the fixing means comprises inter-engaging formations provided on the mountings.

14. Apparatus as claimed in any of Claims 11 to 13 wherein the first mounting comprises a ring mounted in the sleeve at the entry thereof.

15. Apparatus as claimed in Claim 14 wherein the second mounting comprises a ring to which the sealing material is attached.

16. Apparatus as claimed in any of Claims 1 to 8 wherein the entry sealing means comprises a first sealing element provided in the entry and a second sealing entry provided on a surgical glove, the sealing elements inter-engaging to seal the sleeve on passing of the glove through the entry.

17. Apparatus substantially as hereinbefore described with reference to the accompanying drawings.

CRUICKSHANK & CO.,

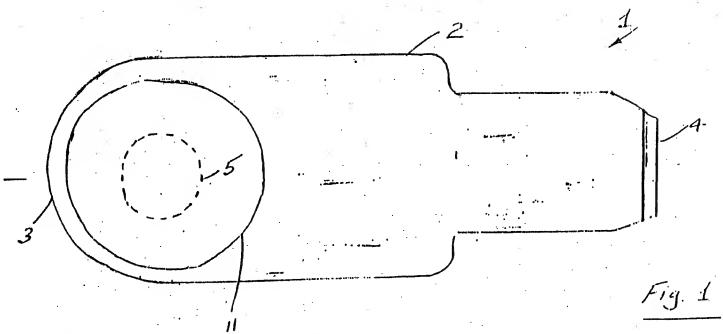


Fig. 1

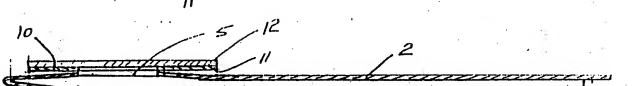


Fig 2

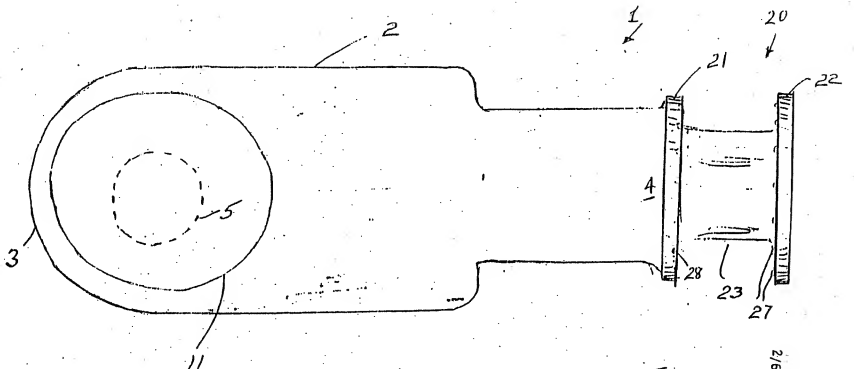


Fig. 3

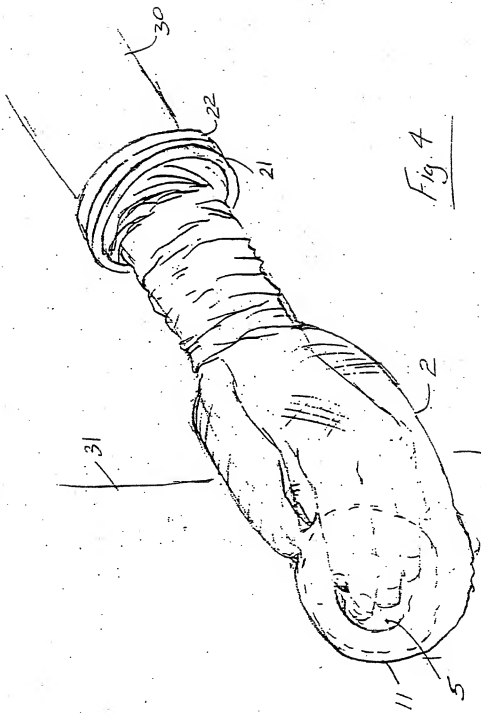


Fig. 4

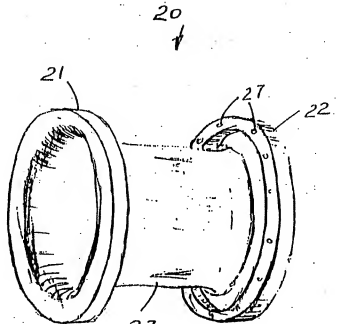


Fig. 5

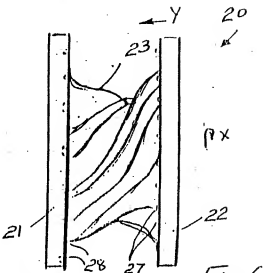


Fig 6

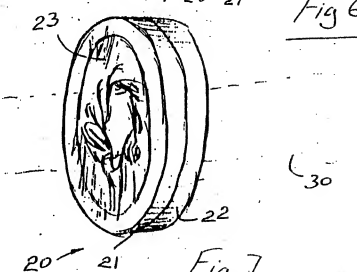


Fig. 7

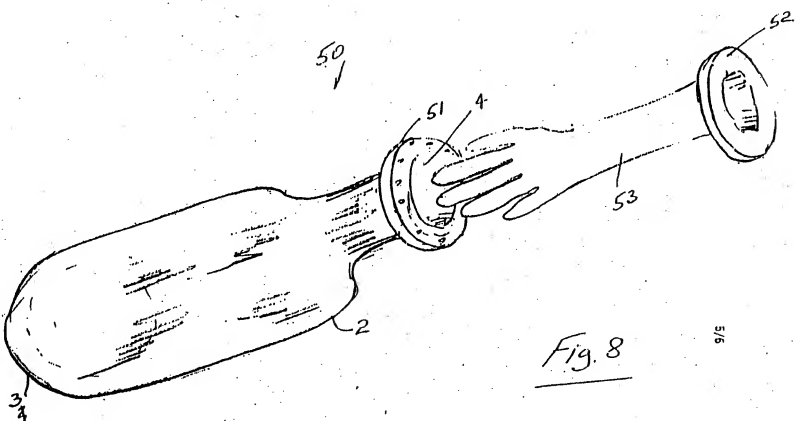


Fig. 8

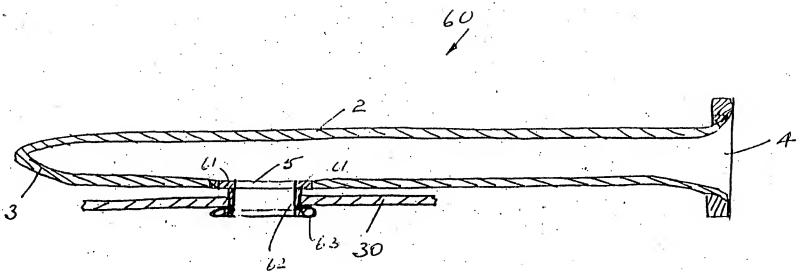


Fig. 9

EXHIBIT F

This opinion was not written for publication and is not binding precedent of the Board

Paper No. 39

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

FRANK BONADIO and ALAN REID,

Junior Party,[1]

v.

PATRICK F. LEAHY, BERWYN M. CROOK, and ROBERT D. RAMBO,

Senior Party.[2]

Patent Interference No. 104,195

JUDGMENT UNDER 37 CFR §§ 1.652 AND 1.656(i)

Before Metz, Pate, and MARTIN, Administrative Patent Judges.

[1] Application 08/641,811, filed May 2, 1996. Assigned to Encoret Limited, Ireland. Accorded the benefit of PCT International Application No. PCT/IE94/00045, filed September 6, 1994.

[2] Patent 5,640,977, issued June 24, 1997, based on Application 08/300,346, filed September 2, 1994. Assigned to Medical Creative Technologies, Inc. Accorded the benefit of: none.

MARTIN, Administrative Patent Judge.

Junior party Bonadio et al. did not respond to the July 19, 2001, order giving them fifteen days to show cause why judgment on the issue of priority/derivation should not be entered against their involved claims pursuant to 37 CFR §§ 1.652 and 1.656(i) because they failed to file a record or an opening brief. Judgment is accordingly entered against Bonadio et al.'s claims that correspond to the count, i.e., claims 5, 6, 8-10, 17, and 25-61, which means Bonadio et al. are not entitled to a patent containing those claims. Judgement is awarded in favor of Leahy et al.'s claims that correspond to the count, i.e., claims 1-31, which means Leahy et al. are entitled to a patent containing those claims.

ANDREW H. METZ
Administrative Patent Judge

WILLIAM F. PATE III
Administrative Patent Judge

JOHN C. MARTIN
Administrative Patent Judge

BOARD OF PATENT APPEALS AND INTERFERENCES

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